April 19, 2023

Wuhan Lotuxs Technology Co., Ltd.
℅ Na Wu
Management Representative
Tacro Guangzhou Branch
501/E2, Future city, No.999 High-Tech Avenue
(Free Trade Zone/Wuhan Area)
Wuhan, 430206
China

Re: K230090
Trade/Device Name: Diode Laser Hair Removal
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: OHT
Dated: January 4, 2023
Received: January 12, 2023

Dear Na Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin K. Chen -S

for

Jianting Wang
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K230090

Device Name
Diode Laser Hair Removal

Indications for Use *(Describe)*
Diode Laser Hair Removal is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. Diode Laser Hair Removal is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

"510(k) Summary" as required by 21 CFR Part 807.92.

Date: 2023-04-14

I. Submitter

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III. Device

Type of 510(k): Traditional
Common Name: Powered laser surgical instrument
Trade Name: Diode Laser Hair Removal
Model: LHR-V8S-810, LHR-V8-810, LHR-V4S-810, LHR-V4-810
Classification Name: Light Based Over-The-Counter Hair Removal
Regulation Number: 21 CFR 878.4810
Review Panel: General & Plastic Surgery
Regulatory Class: II
Product Code: OHT

IV. Predicate Device

Applicant	Predicate Device	510(k) Number
Wuhan Lotuxs Technology Company, Ltd.	SILKPRO Laser Hair Removal System	K142845

510(k)s –Section 6. 510(k) Summary

V. Device Description

The Diode Laser Hair Removal device models LHR-V8S-810, LHR-V8-810, LHR-V4S-810, and LHR-V4-810 emit pulses of invisible infrared laser light of 810nm wavelength that penetrates into the skin and is selectively absorbed by melanin in the hair follicles. This creates a localized thermal effect that disrupts hair growth from the hair follicles. The device contains a sensor that detects contact with the skin so that the device will only emit the infrared laser pulses when the sensor is in contact with the skin. The device also includes a skin cooling feature and the device is powered by an external AC/DC power adaptor.

VI. Indications for Use

Diode Laser Hair Removal is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. SILKPRO is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

VII. Comparison of Technological Characteristics With the Predicate Device

A technical comparison to the predicate is provided below:

Comparison Elements	Subject Device	Predicate Device
K Number	Applying	K142845
Trade name	Diode Laser Hair Removal	SILKPRO Laser Hair Removal System
Model	LHR-V8S-810, LHR-V8-810, LHR-V4S-810, LHR-V4-810	/
Classification name	Light Based Over-The-Counter Hair Removal	Light Based Over-The-Counter Hair Removal
Product code	OHT	OHT
Intended use/Indications for Use	Diode Laser Hair Removal is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. Diode Laser Hair Removal is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.	SILKPRO is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. SILKPRO is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.
Laser Type	Diode laser	Diode laser
Laser Material	GaAs	GaAs
Wavelength	810nm	810nm
Max Energy Density	LHR-V8S-810, LHR-V8-810: 9.0J/cm²	25J/cm²
	LHR-V4S-810, LHR-V4-810: 7.0J/cm²	

510(k)s –Section 6. 510(k) Summary

Comparison Elements	Subject Device	Predicate Device
Energy Density	LHR-V8S-810, LHR-V8-810: 2.2J/cm², 3.4J/cm², 4.5J/cm², 5.6J/cm², 7.0J/cm², 9.0J/cm² LHR-V4S-810, LHR-V4-810: 2.0J/cm², 2.8J/cm², 3.5J/cm² 4.3J/cm², 5.3J/cm², 7.0J/cm²	5J/cm², 10J/cm², 15J/cm², 20J/cm², 25J/cm²
Treatment Window Size	30mm×10mm	9mm×9mm
Safety feature	Complied with IEC 60601-1, IEC 60601-1-11, IEC60601-1-2, IEC 60601-2-22 and IEC 60825-1	Complied with IEC 60601-1, IEC 60601-1-11, IEC60601-1-2, IEC 60601-2-22 and IEC 60825-1
Biocompatibility	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10

VIII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1)**Biocompatibility Testing**

The biocompatibility evaluation for the body-contacting components of Diode Laser Hair Removal was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices -Part 1: Evaluation and Testing Within a Risk Management Process, Document Issued on June 16, 2016", as recognized by FDA. The testing was performed to, and passed, including:

- ISO 10993-5:2009/(R)2014, Biological Evaluation of Medical Devices –Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010, Biological Evaluation of Medical Devices –Part 10: Tests for Irritation and Skin Sensitization

2)**Electrical, EMC, and laser output, Safety and Performance Testing**

Electrical, EMC, and laser output, Safety and Performance Testing was performed to, and passed, the following standards:

- IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Medical electrical equipment –Part 1-11: General requirements for basic safety and essential performance –Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility – Requirements and tests
- IEC 60601-2-22 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60825-1 Safety of laser products - Part 1: Equipment classification, and requirements

Summary

Based on the above performance as documented in this application, Diode Laser Hair Removal was found to have a safety and effectiveness profile that is same as the predicate device.

VIII. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, Diode Laser Hair Removal is considered to be substantially equivalent to the predicate device K142845.